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K091852

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Appendix A (Summary of Safety And Effectiveness)

Submitter:
John Gagliardi, President **(contact person)** and official correspondent for RTC)
MidWest Process Innovation, LLC
7736 Woodside Court
Maineville, OH 45039
513-573-0085 (Telephone and fax) **or**
513-573-0519 (Telephone and fax)
JGAGL777@One.Net

Trade Name: Refractron Technologies Corporation Bisque Zirconia Blanks

Common Name: Refractron Technology Corporation Bisque Zirconia Blanks

Classification Name: Porcelain Powder for Clinical Use

Summary of Safety and Effectiveness:

The Refractron Bisque Zirconia Blank is substantially equivalent in function and intended use to the Zircar Zirconia, Inc. Bisque Zirconia Blanks – K081850. This predicate device is presently on the market.

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. As such, it has been shown in this pre-market notification submission, that the differences between the Refractron Porcelain Powder Blanks and the Zircar Zirconia Blanks do not raise any questions regarding their safety and effectiveness. They are, as explained below, the same product

The Refractron Porcelain Powder Blanks, as designed and manufactured, are as exactly safe and effective as the predicate device and therefore are determined to be substantially equivalent to the referred predicate device. They are in fact, one-in-the same.

Note: Zircar Zirconia Blanks (the predicate device designated for this Pre-Market Notification submitted by Refractron Technologies Corporation, Newark, NY are actually, on a day-to-day basis, produced for Zircar Zirconia, Inc., PO Box 287, Florida, NY 10921-0287, i.e. the actual Bisque Zirconia Blanks so mentioned in K081850 are a product manufactured by Refractron Technologies Corporation for Zircar Zirconia, Inc. Zircar Zirconia, Inc. has only one supplier for these blanks, i.e. Refractron Technologies Corporation.

Refractron Porcelain Powder Blanks are high purity, bisque fired zirconia machining blanks. The powders pressed to form these blanks are of a uniform size and well dispersed, ensuring no agglomerates. The resultant fine-grained, bisque body allows intricate shapes to be machined with specified tolerances. Refractron Technologies Corporation Blanks **(exactly Zircar Zirconia, Inc. Blanks)** are dental ceramic blanks designed for the manufacturing of substructures for ceramic dental appliances. The dental appliance is machined either by CAD/CAM machining or using the copying technique. Products are either porous or dense. Porous blanks can then be sintered to full density and strength. Dense blanks do not need a final heat treatment and are therefore ready for veneering immediately after machining. All appliances are for the sole use of the particular patient only. At the dental lab (Refractron's customer that processes the blanks) a metal chuck is glued on the end of the blank that holds it in the CAD/CAM machine which is used to machine the final dental restoration. At the completion of the machining steps, the dental restoration is fired, i.e. sintered, in the oven to harden the ZrO_2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 1 0 2009

Refractron Technologies, Incorporated
C/O Mr. John Gagliardi
President
MidWest Process Innovation, L.L.C.
7736 Woodside Court
Maineville, Ohio 45039

Re: K091852
Trade/Device Name: Bisque Zirconia Blanks RG10191, RG10210, RG10211, and RG10205
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 19, 2009
Received: June 23, 2009

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091852

1081

INDICATIONS FOR USE

510(k) Number (if known): Not known at this time.

Classification Name: Porcelain Powder For Clinical Use

Device Name: Refractron Technologies Corporation Bisque Zirconia Blanks

Indications for Use: Refractron Technologies Corporation Bisque Zirconia Blanks (Type BYZ), are indicated for use as a substructure for ceramic dental restorations.

Sizes: Various sizes and shapes, e.g. rectangular, disk-shaped, square, etc. and similar to the sizes mentioned in K081850

__x__ **Prescription Use Only: All blanks are sold by or on the order of a dental professional. They are not for use by the general public or over the counter (OTC).**

Per Part 21 CFR 801, Subpart D

(Please Do Not write below this line-continue on another page as needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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